

ZMR[®] Hip System-XL
Summary of Safety and Effectiveness

K031572, page 14/2

Submitter: Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Contact Person: Karen Cain
Manager, Regulatory Affairs
Telephone: (574) 372-4219
Fax: (574) 372-4605

Date: May 16, 2003

Trade Name: ZMR[®] Hip System-XL

Common Name: Total hip prosthesis

Classification Name and Reference: Hip joint metal/polymer semiconstrained uncemented prosthesis, no 21 CFR reference
Hip joint metal/polymer/metal semiconstrained porous coated uncemented prosthesis, 21 CFR 888.3358

Predicate Devices: ZMR[®] Hip System-Revision Taper, manufactured by Zimmer, Inc., K992667, cleared October 27, 1999
ZMR[®] Hip System-Porous Revision, manufactured by Zimmer, Inc., K994286, cleared March 10, 2000

Device Description: Like its predicates, the ZMR[®] Hip System-XL prosthesis is a modular femoral stem manufactured from *Tivanium*[®] Ti-6Al-4V Alloy and intended for cementless use in revision hip arthroplasty. This device has two modular junctions: a head/neck junction and a midstem junction. Three components are intraoperatively assembled to construct the device: a proximal "body," a distal stem, and a compression nut.

Intended Use:

The ZMR[®] Hip Prosthesis is intended for revision hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur.

Comparison to Predicate Device:

The modifications to the ZMR[®] Hip System change neither the intended use nor the fundamental scientific technology of the device. The ZMR XL components are manufactured, packaged and sterilized using the same processes and materials.

Performance Data:

Non-clinical performance testing demonstrated that the device is equivalent to the predicate.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2003

Ms. Karen Cain
Manager, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Re: K031572
Trade/Device Name: ZMR[®] Hip System-XL
Regulation Number: 21 CFR 888.3358 and 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis and Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: LPH and LWJ
Dated: May 16, 2003
Received: June 3, 2003

Dear Ms. Cain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

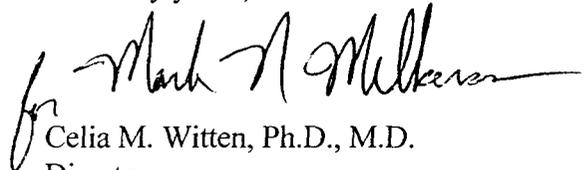
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 - Ms. Karen Cain

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark A. Milkerson". The signature is written in a cursive style and is positioned above the typed name of the signatory.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

JUN 24 2003
Indications for Use

Page 1 of 1

510(k) Number (if known): K031572

Device Name:

ZMR[®] Hip System-XL

Indications for Use:

The ZMR Hip Prosthesis is indicated for total hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur. Arthroplasty should be performed only when more conservative methods of treatment have failed to provide symptomatic relief or when there is progressive disability.

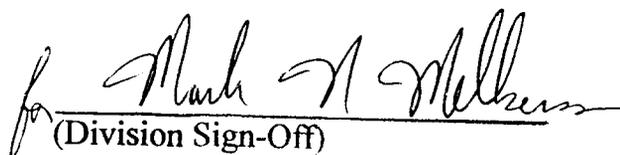
(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No
(Optional Format 1-2-96)



(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031572